

## **REMARKS**

Applicant and Applicant's attorney express appreciation to the Examiner for the courtesies extended during the recent interview held on January 10, 2008. Reconsideration and allowance for the above-identified application are now respectfully requested in view of the foregoing amendments and the following remarks. Claims 1-19 and 21-36 are pending, wherein claims 1-18 and 21-35 have been amended, claim 20 was cancelled, and new claim 36 was added.

### **I. RESTRICTION REQUIREMENT**

Claims 1-13 were amended so as to depend from claim 14. Independent claims 25 and 30 were amended in order to more particularly fall within elected invention II. Claim 14 recites a method for locally treating pathogen-induced disordered tissue caused by at least one of a virus, a bacteria or a fungus. Claims 25 and 30 were amended to claim this same category of treatment. Accordingly, all the claims as now presented fall within elected invention II. Support for local (*i.e.*, non-systemic) treatment of disordered tissue is found at page 27, line 24 – page 28, line 2.

### **II. INFORMATION DISCLOSURE STATEMENT**

The Office Action indicates that the previously filed information disclosure statement did not include legible copies of all foreign patents and non patent literature listed therein. Applicant notes that such references were either provided by the Applicant or else cited by the USPTO in one or more previously filed applications to which the present application claims the benefit of under 35 U.S.C. § 120 (*i.e.*, U.S. Application No. 10/200,897, filed July 22, 2002; U.S. application No. 09/668,953, filed September 22, 2000, now U.S. Patent No. 6,423,750; and U.S. Application No. 09/401,076, filed September 22, 1999, now U.S. Pat. No. 6,211,243). Inspection of U.S. Patent No. 6,211,243 reveals that each of the foreign patents and non patent literature that were crossed out by the examiner is listed on the cover page of this patent, indicating that such references are or should be found in the official file history of this patent at the USPTO. Notwithstanding the foregoing, and in an effort to help the examiner find at least some of the crossed-out references, a search was performed in Applicant's patent files in an effort to locate copies of the cross-out references. While not all of the references could be located, Applicants are submitting or will submit courtesy copies of the references that were

found, together with a new Information Disclosure Statement, Form PTO-1449, and a submission fee.

### **III. REJECTION UNDER 35 U.S.C. § 112**

The Office Action rejects claims 14-24 under 35 U.S.C. § 112, second paragraph, on the grounds that the term "rapidly diffusing" is allegedly indefinite. Although Applicant believes this is a relative term that would be understood by those of skill in the art, Applicant has amended the claims to remove this term, thereby rendering this rejection moot.

### **IV. ART REJECTIONS**

The Office Action rejects claims 14-17, 19 and 21 under U.S.C. § 102(b) as being anticipated by US 5,753,270 to Beauchamp et al. and claims 18, 20 and 22-24 as being unpatentable over Beauchamp and Remington's Pharmaceutical Sciences, 1975 (Remington's). Applicant submits that the claims as amended are neither anticipated by, nor obvious over, Beauchamp, either alone or in combination with any other art of record, such as Remington's.

Claim 1 as amended claims a method for locally treating pathogen-induced disordered tissue caused by at least one of a virus, a bacteria or a fungus comprising (1) identifying disordered tissue, (2) providing a treatment composition comprising an anti-infective agent in a carrier, the anti-infective agent comprising an organohalide, wherein the treatment composition is a liquid comprising a tissue penetrating agent for penetrating skin, and (3) applying the treatment composition to the disordered tissue in a manner so as to cause or allow the treatment composition to form a reservoir of the treatment composition within the stratum spinosum of the disordered tissue so as to provide treatment of the disordered tissue. Support for causing or allowing the treatment composition to form a reservoir of the treatment composition within the stratum spinosum of the disordered tissue is found generally at page 18, line 1 – page 19, line 13 and Figure 1 of the application, and more specifically at page 19, lines 3-13 and page 27, line 19 – page 28, line 2. Forming a reservoir of the treatment composition within the stratum spinosum permits the treatment composition to diffuse into infected areas of the disordered tissue requiring treatment. Application, page 27, lines 24-25.

The formation of a reservoir of treatment composition within the stratum spinosum is the synergistic result of two different aspects of the invention: (1) the formulation of the treatment composition and (2) the manner in which the treatment composition is applied (e.g., by rubbing

and/or compressing the disordered tissue while applying the composition). *See* Application, page 8, lines 18-24; page 9, lines 2-6. The claimed combination of providing a penetrating treatment composition as claimed, coupled with applying the treatment composition in a manner that causes or allows the treatment composition to form a reservoir of the treatment composition within the stratum spinosum, is neither taught nor suggested in either Beauchamp or any other art of record.

In contrast to the combined action of the composition and method recited in claim 14 as amended, Beauchamp discloses a composition that is applied multiple times in close succession in order to achieve the desired result. As pointed out at page 6, lines 8-13 of the Application, the methodology described in Beauchamp involves applying the disclosed composition to the afflicted area 3 to 4 times over a one minute period. This sequence is then repeated every 3 minutes over a 10 minute period. The entire procedure is then repeated after approximately 1/2 to 1 hour for 2 to 3 hours or until activity is stopped and healing is evident. The foregoing procedure requires applying the Beauchamp composition to the afflicted area approximately 24-48 times. The methodology used to apply the Beauchamp composition included the use of a cotton swab, which implies that the composition was dabbed onto the surface of the afflicted tissue with minimal pressure and/or rubbing. Col. 6, lines 10-11. Although Beauchamp teaches that some penetration of the composition into the skin is possible, it is unlikely that the composition in fact penetrated sufficiently through the skin in a manner so as to form a reservoir of the treatment composition in the stratum spinosum and that could thereafter be available to treat the disordered tissue. Otherwise, it would not have been necessary to apply and reapply the Beauchamp composition approximately 24-48 times over a 2-3 hour period. It would be difficult and highly cumbersome to follow the Beauchamp regimen every time it is desired to treat afflicted tissue.

In contrast to Beauchamp, the present invention provides a method of treating composition that appears to be much easier to comply with. Rather than relying on numerous and frequent applications of a treatment composition (*e.g.*, 24-48 times over 2-3 hours) as in Beauchamp, the claimed composition and method are effective using far fewer applications (*e.g.*, applying the composition all at once and/or in one or two applications). *See* Application, page 19, lines 10-20. It is much simpler to deliver a relatively large quantity of the claimed treatment composition to form a reservoir of the treatment composition in the stratum spinosum rather than dabbing the treatment composition of Beauchamp using a cotton swab or other similar applicator

onto the afflicted tissue 24-48 times over a 2-3 hour period as instructed by Beauchamp. Applicant therefore submits that claim 14 as amended is neither anticipated by, nor obvious over, Beauchamp, either alone or in combination with any other art of record.

For example, the Office Action combines Beauchamp with Remington's Pharmaceutical Sciences, p. 685 in rejecting claims that recite vigorously rubbing the disordered tissue while applying the treatment composition. The problem with this combination is that Remington's does not disclose a method for enhancing local, topical treatment of a skin disorder. Rather, Remington's discloses a method of achieving *systemic* circulation of a drug within a person by vigorously rubbing a drug into a person's hair follicles in a manner that causes the drug to penetrate through the skin and into the patient's "circulation". The quantity of benzethonium chloride component found in the Beauchamp composition (*i.e.*, 0.2%) is not suitable for ingestion and/or rapid diffusion into the bloodstream system because it is highly toxic. *See* Application, page 22, lines 9-11. Moreover, Beauchamp neither teaches nor suggests the desirability of applying the disclosed composition in any manner other than topical application. Beauchamp certainly does not suggest the desirability of applying the disclosed composition in a manner that would cause it to pass through the patient's skin and into the patient's systemic circulation, which is the desired result according to the application method disclosed in Remington's. One of skill in the art would not have been motivated to modify the purely topical application method of Beauchamp with the systemic circulation introduction method of Remington's, as the result might be dangerous or even toxic to the patient (*i.e.*, the benzethonium chloride component found in the Beauchamp composition is not suitable for ingestion or systemic circulation because it is highly toxic). Accordingly, Applicant submits that it would be improper to combine Beauchamp with Remington's in the manner urged in the Office Action,

Moreover, even if one were to combine Beauchamp and Remington's, the resulting combination does not teach or suggest the combination of elements recited in claim 14 as amended. The purpose of the method taught under the heading "Topical Route" of Remington's is to achieve "systemic circulation to cause systemic effects." Remington's teaches that absorption through topical administration to achieve "*systemic effects*... is too erratic for the topical route to be used for systemic therapy. Recent work with aprotic solvent vehicles has, however, renewed interest in topical administration for *systemic effects*". To achieve better systemic effects, Remington's discloses a method of vigorously rubbing a medicament over hair follicles, which forces the preparation into the hair follicles and glands. "Since much of a drug

that is absorbed through the epidermis diffuses into the circulation *without reaching a high concentration in some portions of the dermis*, systemic administration may be preferred in lieu of or in addition to topical administration." Remington's therefore does not teach or suggest a method of application, in combination with the selection of a treatment composition, that together synergistically cause the treatment composition to form a reservoir of the treatment composition within the stratum spinosum of the disordered tissue so as to provide treatment of the disordered tissue. Thus, even if one were to combine the teachings of Beauchamp and Remington's, one would not readily achieve and/or appreciate the method of claim 14 absent undue testing to determine the desirability of forming a reservoir of the treatment composition within the stratum spinosum of the disordered tissue so as to provide localized, rather than systemic, treatment of the disordered tissue. In short, Beauchamp apparently discloses a combination of composition and method that apparently results in too little penetration of the treatment composition. That is evident by the fact that the Beauchamp composition was applied 24-48 times over a 2-3 hour period to achieve the desired results. At the opposite end of the spectrum, Remington's discloses a method that apparently results in penetration of a medicament through a person's hair follicles and glands to achieve "systemic circulation" of the drug. Claim 14, by contrast, claims the use of a composition and application method that achieves a different result than either Beauchamp or Remington's.

Dependent claims 1-13, 15-19 and 36 recite additional limitation that further distinguish over the art of record. For example, claim 1 as amended claims the use of a treatment composition in which the organohalide comprises at least one quaternary ammonium halide compound having an alkyl radical with at least six carbons. Support for this can be found at page 20, lines 12-14 and page 22, line 13 of the Application. Such compounds were found to be particularly effective in treating disordered tissue. Beauchamp only discloses a single example of a quaternary ammonium halide compound, namely benzethonium chloride, which includes a two-carbon alkyl group (*i.e.*, an ethyl radical). Beauchamp neither teaches nor suggests the use of a composition as in claim 1 as amended.

Dependent claims 2, 3 and 15 claim compounds comprised of alkyl groups with a number of carbons, as taught at page 20, line 21, page 21, line 14 and page 22, line 13, which are neither taught nor suggested by Beauchamp. Other claims recite the inclusion of specific quantities of isopropyl alcohol and water which are neither taught nor suggested by Beauchamp and which

were found to be particularly effective in causing rapid penetration of the treatment composition into the stratum spinosum.

Claim 10 claims the use of a treatment composition that is substantially oil free, as taught at page 33, line 9 of the Application, which helps maximize penetration. In contrast, Beauchamp discloses compositions that include oils such as menthol, thymol and eucalyptol, which may inhibit penetration compared to compositions that omit such substances. Claim 19 alternatively claims a composition that is substantially free of penetration inhibiting components.

Claim 22 alternatively claims a method in which the treatment composition is applied to the disordered tissue by compressing the disordered tissue with little or no rubbing. Support for this is found at page 17, lines 2-7 of the Application (teaching application by "either... compressing ... and/or by rubbing"). The combination of Beauchamp and Remington's neither teaches nor suggests applying a treatment composition in the manner recited in claim 22.

Claim 23 claims treatment of disordered tissue including one or more lesions caused by smallpox virus, and claim 24 claims treatment of disordered tissue including one or more lesions caused by anthrax bacteria. The combination of Beauchamp and Remington's neither teaches nor suggests treating lesions caused by smallpox and/or anthrax. New claim 36 claims treatment of disordered tissue including one or more lesions caused by a herpes virus.

Claim 25 as amended alternatively claims a method for locally treating pathogen-induced disordered tissue caused by at least one of a virus, a bacteria, or a fungus comprising (1) identifying disordered tissue that comprises one or more lesions caused by at least one of a virus, a bacteria, or a fungus, (2) providing a treatment composition comprising at least one anti-infective agent in a carrier, the anti-infective agent comprising an organohalide, and wherein the treatment composition is a liquid comprising a tissue penetrating agent for penetrating skin, and (3) applying the treatment composition to the disordered tissue by rubbing in a manner so as to cause or allow said treatment composition to form a reservoir of the treatment composition within the disordered tissue in order for the treatment composition to kill at least one of viruses, bacteria or fungus within the disordered tissue before diffusing beyond the disordered tissue. Support for a method in which a reservoir of treatment composition is formed within the disordered tissue in order to attack and kill pathogens before diffusing beyond the disordered tissue is found at page 19, lines 21-23; page 27, line 19 – page 28, line 2.

As discussed above, Beauchamp apparently discloses a combination of composition and method that apparently results in too little penetration of the treatment composition to form a

reservoir within the disordered tissue. That is evident by the fact that the Beauchamp composition was applied 24-48 times over a 2-3 hour period to achieve the desired results. At the opposite end of the spectrum, Remington's discloses a method that apparently results in penetration of a medicament through a person's hair follicles and glands to achieve "systemic circulation" of the drug. Claim 25, by contrast, claims the use of a composition and application method that achieves a different result than either Beauchamp or Remington's.

Claim 30 as amended alternatively claims a method for locally treating pathogen-induced disordered tissue caused by at least one of a virus, a bacteria, or a fungus comprising (1) identifying disordered tissue that comprises one or more lesions caused by at least one of a virus, a bacteria, or a fungus, (2) providing a treatment composition comprising at least one anti-infective agent in a carrier, the anti-infective agent comprising an organohalide, and wherein the treatment composition comprises a tissue penetrating agent for penetrating skin, and (3) applying the treatment composition to the disordered tissue while maintaining sufficient pressure on the disordered tissue so as to firmly compress the disordered tissue against at least one of bone, tooth, gum, or other tissue underlying the disordered tissue in order to assist penetration of the treatment composition into the disordered tissue.

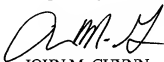
As discussed above, Beauchamp apparently discloses a combination of composition and method that apparently results in too little penetration of the treatment composition to form a reservoir within the disordered tissue. That is evident by the fact that the Beauchamp composition was applied 24-48 times over a 2-3 hour period to achieve the desired results. At the opposite end of the spectrum, Remington's discloses a method that apparently results in penetration of a medicament through a person's hair follicles and glands to achieve "systemic circulation" of the drug. Moreover, Remington's does not teach or suggest any method that includes the act of applying a treatment composition to disordered tissue while maintaining sufficient pressure on the disordered tissue so as to firmly compress the disordered tissue against at least one of bone, tooth, gum, or other tissue underlying the disordered tissue in order to assist penetration of the treatment composition into the disordered tissue. Claim 30, by contrast, claims the use of a composition and application method that achieves a different result than either Beauchamp or Remington's.

#### IV. CONCLUSION

In view of the foregoing, Applicant submits that the application is now in allowable condition. In the event the Examiner finds any remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview or which may be overcome by Examiner amendment, the Examiner is requested to contact the undersigned attorney.

Dated this 25<sup>th</sup> day of January 2008.

Respectfully submitted,



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